

Neonicotinoids: Status Update and Path Forward

April 29, 2021

Draft, Internal, Deliberative, Confidential Material



Overview



- The team is briefing on the updates to the neonicotinoids' registration review timeline to allow for early ESA mitigation
 - While the Interim Decisions currently include the most extensive suite of mitigation measures for reducing pollinator risk proposed to date for any insecticide, they do not address risks to endangered species

Presentation Outline

- Background (neonicotinoid chemical usage and registration review)
- Mitigation
- Endangered Species Assessments
- Future Considerations

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Background

EPA Regulatory History

- **2008** – Registration review of imidacloprid began
 - Public concern over honeybee incidents
- **2011** – Registration review for remaining N-substituted neonicotinoids aligned
- **2013** – Pollinator protection labelling required*
- **2015** – Hold placed on granting new outdoor uses/expansion which could increase risk to pollinators
- **2016 & 2017** – Preliminary Pollinator Assessments released
 - Over 1 million comments received across the active ingredients, with ~700 substantive comments
- **March 2019** – ESA lawsuit leads to 12 clothianidin/thiamethoxam voluntary product cancellations
- **February 2020** – Proposed Interim Decisions (PIDs), Final Bee Risk Assessments, and other supporting documents issued

State Actions

Bans on consumer sales and use – CT, MA, MD
Use restrictions – CA, NY, OR, VT

International Actions

Phasing out most outdoor uses – Canada
Ban on outdoor uses – EU, UK, FR

Petitions

- **2012** – CFS Clothianidin
- **2017** – Seed Treatment
- **2020** – NRDC Tolerance

Litigation

- **2017** – Ellis v. Keigwin (clothianidin & thiamethoxam)
- **2017** – NRDC filed suit (acetamiprid, dinotefuran and imidacloprid)
- **2021** – Joint motion (imidacloprid)
- **2021** – NRDC Summary judgment motion



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* https://www.epa.gov/sites/default/files/2013-11/documents/bee_label_info_16.pdf



Background

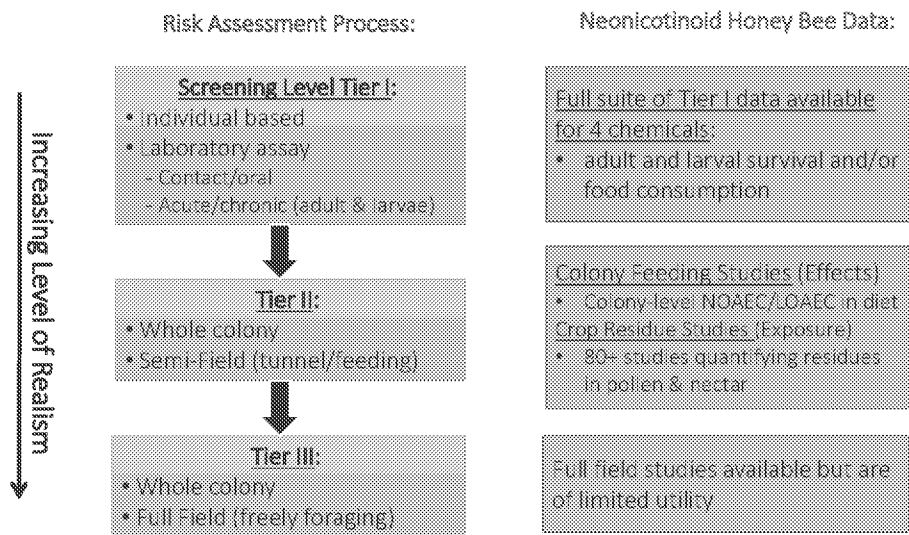


- Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam are nitroguanidine-substituted neonicotinoids; Acetamiprid is a cyano-substituted neonicotinoid
 - Provide both contact and systemic protection
 - Registered for seed treatments, foliar (ground and air), soil applications, and tree injections
 - Registered for field and specialty crops, forestry, turf and ornamentals, livestock areas, as well as other residential and commercial indoor/outdoor uses (including pet products)
- Usage
 - Seed treatments with clothianidin, imidacloprid very common; acetamiprid, thiamethoxam also widespread
 - Foliar applications account for substantial acreage
 - Soil applications account for less acreage, but typically utilize relatively high application rates
 - Imidacloprid is a prominent insecticide for use in nursery ornamentals
 - Imidacloprid, and to a lesser extent clothianidin, are commonly used for residential and commercial pest management

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Background – Tiered Approach to Assessing Risks to Bees



Background – Assessment Conclusions



Human Health Risks of Concern

- Limited Occupational Handler Risks of Concern (all except dinotefuran)
- Residential Exposure from Turf Use (imidacloprid only)
- No acute or chronic dietary

Ecological Risks of Concern

- Pollinators (bees) – Risks identified for all chemicals from majority of bee-attractive plants (both ag and non-ag) (Risk from Foliar > Soil > Seed Treatment)
- Birds and Mammals – Risk identified from consuming treated seed (all except dinotefuran); Foliar and soil risks (Clothianidin, Imidacloprid)
- Aquatic Invertebrates – Risk for all 5 chemicals (Foliar > Soil > Seed)

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Background – Assessment Conclusions



Benefits Conclusions

- Foliar applications provide long-lasting control of many pests and are valuable for pests that are difficult to reach with contact-only insecticides (*e.g.*, internal fruit feeders, aphids)
- Seed treatments are valuable in protecting germinating plants from soil dwelling and early season pests, including those that vector disease
- Soil Treatments are useful for the control of soil dwelling and early season pests and for systemic control via irrigation
- Available alternatives differ by site, pest, and application method
 - Most sites: organophosphates, pyrethroids, carbamates (broad-spectrum, contact)
 - Several situations (*e.g.*, grape, sugarbeet seeds) have no effective alternatives

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Bee Risk Management Approach



- Goal: **Deliberative Process / Ex. 5**

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- Proposed Mitigation for Pollinators

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- Some crops with highest benefits (citrus, cotton, grapes) do not have pollinator mitigation proposed

* Changes to mitigation from PID to ID



Proposed Mitigation - Ecological



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Proposed Mitigation – At-bloom Restriction



Existing Pollinator Protections	Proposed ID Mitigation
<ul style="list-style-type: none">• “Do not apply this product while bees are foraging. Do not apply this product until flowering is complete and all petals have fallen unless one of the following conditions is met:<ul style="list-style-type: none">• The application is made to the target site after sunset• The application is made to the target site when temperatures are below 55°F• The application is made in accordance with a government-initiated public health response• The application is made in accordance with an active state-administered apiary registry program where beekeepers are notified no less than 48-hours prior to the time of the planned application so that the bees can be removed, covered or otherwise protected prior to spraying• The application is made due to an imminent threat of significant crop loss...”	<ul style="list-style-type: none">• Deliberative Process / Ex. 5

Summary of Comments and Issues from the Proposed Interim Decisions



- The agency received approximately 190,000 public comments and mass mailers
 - Roughly 450 of those comments were unique and substantive
 - Comments were received from registrants, grower groups, other professional stakeholders, academia, NGOs, and the general public
 - 60-day public comment period opened on February 3, 2020, but was extended for an additional 30 days and then re-opened for an additional 30 days
- Many commenters (e.g., Bayer, Florida Fruit and Vegetable Association, National Cotton Council, National Landscape Professionals) acknowledged the consideration of benefits in the PIDs
- Many commenters (e.g., Arizona Pest Management Center, BASF, Bayer, USDA) identified issues with the proposed at-bloom restriction and rate reductions
- Comments from NGOs (e.g., Beyond Pesticides, the Center for Biological Diversity, the Center for Food Safety, etc.) reiterated their concern for risks to pollinators, aquatic invertebrates, and birds and mammals. Commenters also challenged the agency's risk-benefit analysis.

Potential Changes to the Mitigation



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- Biological evaluations (BEs) scheduled for imidacloprid, clothianidin, and thiamethoxam (not dinotefuran or acetamiprid)
- Expected outcomes:

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- Draft BEs planned August 2021; 60+ day public comment period

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- Final BEs required in June 2022 under court settlements; may incorporate ID mitigation measures depending on timing
- Unclear when USFWS & NMFS Biological Opinions would be issued, which specify mitigations for Listed species

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Additional Considerations Regarding Delay of ID Publication



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APPENDIX

EPA – PMRA Joint Announcement on Neonicotinoids April 2015



"EPA believes that until the data on pollinator health have been received and appropriate risk assessments completed, it is unlikely to be in a position to determine that such uses would avoid "unreasonable adverse effects on the environment" as required under FIFRA to support *further regulatory expansion* of these pesticides in outdoor settings. Affected actions include:

New or Modified Uses (including crop group expansion requests)

- Changes to Existing Use Patterns (ex. adding aerial or soil application or significant formulation changes)
- Experimental Use Permits
- New Special Local Needs Registrations"

The announcement specified completion of the pollinator risk assessments however, while these assessments have been completed, EPA has not yet lifted the moratorium on new uses or expansion of existing uses.

EPA has a couple new uses and expansion of existing uses (e.g., rate increases, adding aerial application to existing seed treatment) pending for the neonicotinoids (clothianidin and Thiamethoxam).

- ✓ the PRIA dates have been renegotiated multiple times.
- ✓ the pending changes may not be in alignment with the Agency's final neonic mitigation

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NRDC's Tolerance Petition

- Charges that EPA improperly conducted its risk assessments and must revoke all tolerances for the neonicotinoids and cancel all uses which EPA cannot demonstrate meet FFDCA safety standard

- An effective ban on neonics

- EPA plans **Deliberative Process / Ex. 5**

- Allegations and the Agency's Responses are:

1. Use the most sensitive endpoint and appropriate uncertainty factors when calculating the reference dose

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2. Retain the FQPA 10X child safety factor

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NRDC's Tolerance Petition (Cont'd)

3. Assess the cumulative impacts of exposure to the neonic class

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4. Assess aggregate effects of exposure to neonics and all degradates

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5. Conduct an acute dietary risk assessment that accounts for risks to high-exposure individuals

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CFS' Petition Against Clothianidin

- On March 20, 2012, Center for Food Safety (CFS) petitioned on behalf of 27 beekeeper and honey producers, and 4 environmental and consumer organizations
- Petitioners requested that the agency:
 1. "Cure clothianidin's unlawful conditional registration"
 2. Prevent alleged imminent harm by suspending clothianidin's registrations and initiating special review and cancelation proceedings
 3. Suspend and stop sale of allegedly misbranded clothianidin products
 4. Address Endangered Species Act consultation obligations for clothianidin
- On July 12, 2012, the agency opened a docket (EPA-HQ-OPP-2012-0334) to address the petition, and posted an acknowledgement letter that responded to the imminent harm allegation
 - This letter also stated that the agency would address the remaining concerns at a later time

Seed Treatment Petition



- On April 25th, 2017, EPA received a seed treatment petition from the Center for Food Safety (CFS) asking EPA to make a policy determination regarding the treated article exemption as it relates to treated seeds

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Litigation



- In 2017, NRDC filed suit against EPA for failing to meet its ESA obligations on imidacloprid, dinotefuran, and acetamiprid.
- In January 2021, EPA filed a joint motion to have the court enter a partial settlement for imidacloprid that includes EPA finalizing its BEs in June 2022, which aligns with the *Ellis v. Keigwin* case for clothianidin and thiamethoxam.
- On April 15, 2021, EPA received NRDC's summary judgment motion for the two remaining chemicals (acetamiprid and dinotefuran). There are 13 specific products remaining in this case.